Remarks/Arguments:

Applicants thank the examiner for the courtesy of the October 5, 2006 interview, the substance of which is set forth below.

35 U.S.C. § 102

Claims 1-3, 9, 16-18, 24, 31, 32, 36, 54, 56, 62, 70, 72, 78, 86, 91, 113, 115 and 117-119 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,594,651 to St. Ville. Applicants respectfully traverse the rejection of these claims and respectfully submit that these claims are patentable over St. Ville for at least the reasons set forth below.

Independent claim 1 recites features that are neither disclosed nor suggested by St. Ville, namely:

> A system for analyzing medical devices comprising:
>
> a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature(s);
>
> a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and *generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device*; and
>
> a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.*

The Office Action acknowledges on page 6 that St. Ville only teaches generating a finite element model of the object to be manufactured. More particularly, the Office Action states on page 6 that "St. Ville discloses the generation of a model of at least one anatomical feature (column 9, lines 31-38) which is in turn used to generate a finite element model or mesh of a medical device based on the geometric model (column 17, lines 4-6)." (emphasis added). Independent claim 1 recites a mesh generator that generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s).

As explained during the interview, St. Ville does not teach or suggest generating a finite element model or mesh representing both a geometric model of an anatomical feature and a geometric model of a medical device. Instead, St. Ville only teaches generating a finite element model of the object to be manufactured. In response to such argument, the examiner cited St. Ville column 17, lines 4-6 as teaching the generation of a finite element model representing both a geometric model of an anatomical feature and a geometric model of a medical device.

Applicants respectfully submit that St. Ville, when read in its entirety, does not disclose the generation of a finite element model representing both a geometric model of an anatomical feature and a geometric model of a medical device. Continuing from the cited lines 4-6, St. Ville column 17 proceeds to explain:

> a finite element analysis may be performed using the fine mesh model of FIG. 6 which includes 5207 **nodes** and 5040 isoparametric solid **elements**. Both hexahedronal and pentahedronal elements are used in the mesh of FIG. 6 to ensure accurate shape adherence. The previously calculated displacement data {x} defines the displacement at each node of the finite element model.
>
> The loads it is desired to subject the composite hip replacement to are defined. Thus, loads such as walking, one leg stance, etc. are used. The choice of loads depends on the nature of the composite hip replacement being designed. These loads are generally known quantities as noted above, for example, with respect to Hodge et at., "Contact Pressures in the Human Hip Joint Measured In Vivo," Proc. Natl. Acad. Sci. USA, 83,.2879-2883 (1986). These loads define the forces {f} at the nodes of the finite element model.
>
> Since the displacement {x} and forces {f} at the nodes of the finite element model have been defined, the global stiffness matrix [k] may be calculated. Using boolean locating functions or other types of locating functions, the stiffness coefficients **at each of the nodes** are determined. Iterative optimization techniques may be used to calculate **the ideal stiffness properties at the elements of the finite element model**.
>
> These determined stiffness coefficients are matched with stiffness coefficients from a material property data base. The manufacturing parameters corresponding to the matched coefficients are appropriately translated and sequenced to generate manufacturing instructions. **These manufacturing instructions are then supplied to a composite weaving machine and the braider speed and the fiber tension are appropriately controlled to produce the composite hip replacement.**

(emphasis added). Examining this passage of St. Ville in its entirety, it is clear that the finite element model referenced at column 17, line 4, is the fine mesh model illustrated in Fig. 6 which is made up of a plurality of nodes and elements. This passage of St. Ville further explains that the stiffness coefficients and properties are determined **at each node and element**; that

the determined stiffness coefficients are matched, translated and sequenced to generate manufacturing instructions; and then these manufacturing instructions are then supplied to a composite weaving machine and the braider speed and the fiber tension are appropriately controlled **to produce the composite hip replacement**. A stiffness is determined at each and every node and element of the finite element model and those stiffness values are then used to generate instructions for manufacture of the composite hip. It is clear that in this entire passage, only the object to be manufactured is being discussed and that the finite element model only represents the object to be manufactured and not any anatomical feature. The "another layer" referenced by the examiner simply refers to another layer of the composite hip replacement.

Such an interpretation is further supported by the earlier discussion in St. Ville of Figure 6. St. Ville explains at column 12, lines 48-55, the manufacture of the component labeled 601, 602 and 603. As explained therein,

> [f]or example, in the case of the prosthetic hip, regions of both high and low stiffness are required. Using the geometric model and the extracted material property coefficients, the manufacturing process and specifically, the tightness of the weave, can be controlled to provide a region of high stiffness (e.g., the region defined by element 601 in Fig. 6) and a region of low stiffness (e.g., the region defined by element 603 in Fig. 6).

All of the components illustrated in Figure 6 are components of the object to be manufactured. St. Ville fails to teach or suggest a mesh generator that generates a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device.

Furthermore, St. Ville does not teach or suggest simulating an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device. St. Ville only teaches imputing forces and corresponding resultant stresses and/or displacements to determine a desired stiffness coefficient. See column 17, lines 23-26. ("Since the displacement {x} and forces {f} at the nodes of the finite element model have been defined, the global stiffness matrix [k] may be calculated.") The input stresses or deformations in St. Ville are not determined by simulating an interaction between the anatomical features and the medical device. Instead, the input stresses or deformations are only related to the stresses experienced in an in vivo hip. St. Ville explains at column 8, lines 30-35, "If the manufacturer desires the prosthetic hip to respond to forces in the same manner as an

in vivo hip, the 'desired displacements' in the prosthetic hip may, for example, correspond to the displacements generated in an in vivo hip during walking and rising from a chair." St. Ville simply utilizes force distributions found in in vivo studies as indicated at column 8, lines 9-13. There is no teaching or suggestion of a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.

Such a distinction is further emphasized with respect to dependent claims 5-7 which recite, respectively, that the medical device is an endovascular prosthesis; the medical device is a stent graft; and the medical device is a cardiovascular stent. The composite hip replacement of St. Ville completely replaces the in vivo hip, and therefore, can be manufactured with a stiffness matrix to simply reproduce the characteristics of the replaced in vivo hip. In contrast, the medical device as recited in claims 5-7 is positioned within and interacts with the anatomical feature. The medical device must perform in the dynamic environment within the anatomical feature, and therefore, the claimed invention simulates such interaction. The device of St. Ville is not concerned with such interaction and does not teach or suggest simulating such interaction or determining the predicted stresses, strains, and deformations of the medical device.

For at least the foregoing reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 1 is condition for allowance. Claims 2–12, 14, 15, 112 and 113 are dependent upon claim 1, and therefore, should also be allowed for the reasons urged with respect to claim 1. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 16 recites

> A system for analyzing a medical device comprising:
>
> a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a particular individual and generates a geometric model of said anatomical feature(s);
>
> a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and *generates a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said medical device*; and

a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device*.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a mesh generator that generates a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said medical device and a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 16 is condition for allowance. Claims 17-27, 29, 30, 114 and 115 are dependent upon claim 16, and therefore, should also be allowed for the reasons urged with respect to claim 16. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 31 recites

A system for analyzing a medical device comprising:

a mesh generator that receives a geometric model of an *in vitro* anatomical feature and a geometric model of a medical device, and *generates a finite element model or mesh representing both said geometric model of said in vitro anatomical feature and said geometric model of said medical device*; and

a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said *in vitro* anatomical feature and said medical device, load data on said *in vitro* anatomical feature and/or said medical device and *simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations of said medical device*.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a mesh generator that generates a finite element model or mesh representing

both said geometric model of said in vitro anatomical feature and said geometric model of said medical device and a stress/strain/deformation analyzer that simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 31 is condition for allowance. Claims 32-39, 41, 42, 116 and 117 are dependent upon claim 31, and therefore, should also be allowed for the reasons urged with respect to claim 31. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 54 recites

A computer method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature;

generating a geometric model of said anatomical feature(s);

receiving data representing a geometric model of a candidate medical device design;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said candidate medical device design and said anatomical feature(s); and

simulating an interaction between said anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a computer method for analyzing a medical device comprising generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design and simulating an interaction between said anatomical feature(s) and said candidate medical

device design to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 54 is condition for allowance. Claims 55-65, 67-69 and 118 are dependent upon claim 54, and therefore, should also be allowed for the reasons urged with respect to claim 54. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 70 recites

A method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature of a particular individual;

generating a geometric model of said anatomical feature(s);

receiving a geometric model of a candidate medical device;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device;

receiving material properties of said anatomical feature(s) and said candidate medical device;

receiving load data imposed on said anatomical feature(s) and said candidate medical device; and

simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a method for analyzing a medical device comprising generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device and simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that

independent claim 70 is condition for allowance. Claims 71-81 and 83-85 are dependent upon claim 70, and therefore, should also be allowed for the reasons urged with respect to claim 70. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 86 recites

A computer method for analyzing a medical device comprising:

receiving data representing a geometric model of at least one *in vitro* anatomical feature and a geometric model of a candidate medical device design;

generating a finite element model or mesh representing both said geometric model of said in vitro anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said *in vitro* anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said *in vitro* anatomical feature(s) and said candidate medical device design; and

simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a computer method for analyzing a medical device comprising generating a finite element model or mesh representing both said geometric model of said in vitro anatomical feature(s) and said geometric model of said candidate medical device design and simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 86 is condition for allowance. Claims 87-94, 96-98 and 119-123 are dependent upon claim 86, and therefore, should also be allowed for the reasons urged with respect to claim 86. For all of these reasons, reconsideration of these claims is respectfully requested.

35 U.S.C. § 103

Claims 4, 19, 57 and 73 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of U.S. Patent No. 5,880,976 to DiGioia III et al. Claims 5-7, 20-22, 33-35, 58-60, 74-76 and 88-90 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "A Finite Element Treatment of the In-Vivo Loading Conditions of NiTi Vascular Stent and Graft Structures" by F. Whitcher. Claims 8, 23, 61 and 77 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Automated Mesh Generation of an Arterial Bifurcation Based Upon In Vivo MR Images" by Seung Lee et al. Claims 10-12, 25-27, 37-39, 63-65, 67, 79-81, 83, 92-94, 96, 112, 114 and 116 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin. Claims 14-15, 29-30, 41-42, 68-69, 84-85 and 97-98 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey. Claims 55, 71, 87 and 120-123 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Failure of All-ceramic Fixed Partial Dentures in vitro and in vivo: Analysis and Modeling" by J.R. Kelly, J.A. Tesk and J.A. Sorensen.

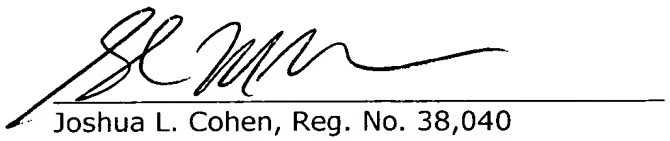
None of these cited references overcome the shortcomings of St. Ville as discussed above in connection with the independent claims. Each of the dependent claims should be allowable for at least its dependence from a respective allowable independent claim.

Conclusion

In view of the amendments and points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested.

If the examiner believes an interview, either telephonic or in person, will advance the prosecution of this matter, it is respectfully requested that the examiner contact the undersigned to arrange the same.

Respectfully submitted,



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